

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

Date: November 17, 1999

MEMORANDUM

SUBJECT: **Etridiazole (Terrazole®)**: HED Product Chemistry and Residue Chemistry Chapters of the RED. Chemical No. 084701. Reregistration Case No. 0009. Case #819299. Submission # S548948. DP Barcode D260516.

FROM: Danette Drew, Chemist
Reregistration Branch 3
Health Effects Division (7509C)

THROUGH: Steve Knizner, Branch Senior Scientist
Reregistration Branch 3
Health Effects Division (7509C)

TO: Roberta Farrell, Chemical Review Manager
Reregistration Branch 2
Special Review and Reregistration Division (7508C)

Attached is the HED Product Chemistry and Residue Chemistry Chapters in support of the etridiazole Reregistration Eligibility Decision. The chapters were prepared by Dynamac Corp. and reviewed by HED with changes made to reflect current HED policy.

cc: D.Drew, List A file, RF, Roberta Farrell (SRRD)
SDI: S.Knizner (11/17/99)

ETRIDIAZOLE (TERRAZOLE)

PC Code 084701; Case 0009

Reregistration Eligibility Decision
Residue Chemistry Considerations

June 16, 1999

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

ETRIDIAZOLE (TERRAZOLE)

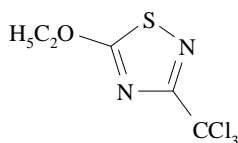
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 084701; Case No. 0009

DESCRIPTION OF CHEMICAL

Etridiazole [5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole] is a soil fungicide and nitrification inhibitor used at planting (in furrow soil treatment) for cotton and for seed treatments of barley, beans, corn, cotton, peanuts, peas, safflower, sorghum, soybeans, and wheat. Etridiazole is also used on turf (golf courses) and ornamentals. There are no homeowner uses.



Empirical Formula:	C ₅ H ₅ Cl ₃ N ₂ OS
Molecular Weight:	247.5
CAS Registry No.:	2593-15-9
PC Code:	084701

IDENTIFICATION OF ACTIVE INGREDIENT

Etridiazole is a reddish-brown liquid with a boiling point of 95 C at 1 mm Hg, specific gravity of 1.5, octanol/water partition coefficient (K_{ow}) of 2.344 x 10³, and vapor pressure of 1.1 x 10⁻² mm Hg at 25 C. Etridiazole is practically insoluble in water (~100 ppm at 25 C), and is soluble in acetone, carbon tetrachloride, ethanol, ether, and xylene. Etridiazole hydrolyzes with acids and bases.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 4/21/99 identified a single etridiazole manufacturing-use product (MP) registered under PC Code 084701: the Uniroyal Chemical Company, Inc. 98.6% technical product (T; EPA Reg. No. 400-413). Only the 98.6% T is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Terrazole Guidance Document dated 9/80 required additional product chemistry data concerning explodability and miscibility (OPPTS 830.6316 and 6319); however, the Terrazole (SRR) Reregistration Standard dated 3/30/89 required that all updated product chemistry data be submitted in support of the reregistration of etridiazole. Data evaluated under the Guidance Document and submitted in response to the Guidance Document requirements were re-evaluated/reviewed under the SRR.

The current status of the product chemistry data requirements for the etridiazole T/TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent product chemistry data requirements are satisfied for the Uniroyal 98.6% T/TGAI, except additional data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Agency has no objections to the reregistration of etridiazole with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 10875
DP Barcode(s): D184741
Subject: Terrazole (Etridiazole) Reregistration: a List A Chemical (Chemical No. 084701; Case No. 0009). Uniroyal Chemical Company: Response to the Terrazole (SRR) Registration Standard (dated 3/30/89) Regarding the Octanol/Water Partition Coefficient (Guideline #63-11) Data Requirements to Support Reregistration of the Uniroyal 95% T (EPA Reg. No. 400-413).
From: F. Toghrol
To: L. Rossi/L. Propst
Dated: 1/8/93
MRID(s): 42515901

CBRS No(s): 12714
DP Barcode(s): D195979
Subject: Terrazole [Etridiazole]. Uniroyal 8/23/93 Response [Series 61, 62, 63 data & CSF for EPA Reg #400-413] to 6/24/92 DCI [3/30/89 SRR]. Rereg. Case 0009.
From: K. Dockter
To: S. Cerrelli
Dated: 3/18/94
MRID(s): 42954701, and 42912201-42912214

CBRS No(s): 13768
DP Barcode(s): D203660
Subject: Etridiazole Reregistration. Uniroyal's 5/13/94 Response [63-17 & -20 data] to 6/24/92 DCI; RE: K. Dockter 3/18/94 Review; CBRS 12714.
From: K. Dockter
To: S. Cerrelli/L. Propst
Dated: 6/22/94
MRID(s): 43232001 and 43232002

CBRS No(s): 15417
DP Barcode(s): D213928
Subject: Etridiazole Reregistration. Uniroyal's 3/10/95 Response [61-1 & 62s data] to "the Agency's review of the product chemistry submissions received 2/10/95... for EPA Reg. No. 400-413."
From: K. Dockter
To: S. Cerrelli/L. Propst
Dated: 5/8/95
MRID(s): 43597401

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00001553 Olin Corporation (1977?) Terrazole® Technical Grade--Data Sheet. (Unpublished study that includes data sheets A.1-A.2, [A.3]-A.4, received Feb 4, 1977 under 1258-812; CDL:095799-A)

00001644 Thomas, R.J. (1976) Chemodynamic Parameter of Terrazole® (5-Ethoxy-3-Trichloromethyl-1,2,4-Thiadiazole) Water Solubility: CASR-19-76. (Unpublished study received Oct 20, 1976 under 1258-812; submitted by Olin Corp., Agricultural Div., Little Rock, Ark.; CDL:228143-B)

00062469 Olin Corporation (1981) [Chemical Studies on Terrazole]. (Unpublished study received Apr 7, 1981 under 1258-812; CDL:244768-C)

00158120 Boynton, H. (1964) Letter sent to R. Philpitt dated Dec 9, 1964: Specifications for chemical 2424. Prepared by Olin. 1 p.

42515901 Batorewicz, W. (1987) Determination of the Partition Coefficient (K_{ow}) for Terrazole: Lab Project Number: 87105. Unpublished study prepared by Uniroyal Chemical Co. 19 p.

42912201 Pierce, J. (1992) Description of Beginning Materials and Manufacturing Process: Terrazole: Lab Project Number: 9246. Unpublished study prepared by Uniroyal Chemical Co. 160 p.

42912202 Pierce, J. (1993) Theoretical Discussion of Impurities: Terrazole: Lab Project Number: 9247. Unpublished study prepared by Uniroyal Chemical Co. 13 p.

42912203 Crutchfield, S. (1993) Terrazole Technical Confidential Statement of Formula: Lab Project Number: 92271. Unpublished study prepared by Uniroyal Chemical Co., Inc. Crop Protection Dept. 57 p.

42912204 Pierce, J. (1993) Explanation of Certified Limits and Confidential Statement of Formula: Etridiazole: Lab Project Number: 9249. 12 p.

42912205 Mitchell, D. (1993) Solubility of Terrazole in Organic Solvents: Lab Project Number: GRL-10311: GRL-FR-10311. Unpublished study prepared by Analytical Chemistry Group, Uniroyal Research Lab. 15 p.

42912206 Mitchell, D. (1993) Solubility of Terrazole in Water and Aqueous Buffer Solutions: Lab Project Number: GRL-FR-10411: GRL-10411. Unpublished study prepared by Uniroyal Chemical Ltd., Research Labs. 17 p.

42912207 Mitchell, D. (1993) Solubility of Terrazole in Industrial Solvents: Lab Project Number: GRL-FR-10412: GRL-10412: 92189. Unpublished study prepared by Analytical Chemistry Group, Uniroyal Research Lab. 15 p.

42912208 Thomson, P. (1993) Determination of the Vapour Pressure for Terrazole Technical Using Gas Saturation: Lab Project Number: GRL-10312: GRL-FR-10312: 9252. Unpublished study prepared by Analytical Chemistry Group, Uniroyal Research Lab. 16 p.

42912209 Thomson, P. (1993) Determination of the Dissociation Constant of Etridiazol, the Active Component in Terrazole Technical: Lab Project Number: GRL-10313: GRL-FR-10313. Unpublished study prepared by Uniroyal Chemical Ltd. Research Labs. 12 p.

42912210 Riggs, A. (1992) The Stability of Terrazole in Sunlight: Lab Project Number: GRL-FR-10317: GRL-10317: 92125. Unpublished study prepared by Uniroyal Chemical Ltd. Research Labs. 15 p.

42912211 Riggs, A. (1992) Accelerated Storage Test for Technical Terrazole: Lab Project Number: GRL-FR-10316: GRL-10316: 9255. Unpublished study prepared by Uniroyal Chemical Ltd., Research Labs. 15 p.

42912212 Riggs, A. (1993) The Stability of Terrazole in the Presence of Metals and Metal Ions: Lab Project Number: GRL-10318: GRL-FR-10318: 92126. Unpublished study prepared by Uniroyal Chemical Ltd., Research Labs. 15 p.

42912213 Thomson, P. (1993) The Oxidizing and Reducing Characteristics of Terrazole Technical: Lab Project Number: GRL-10319: GRL-FR-10319. Unpublished study prepared by Uniroyal Chemical Ltd. Research Labs. 17 p.

42912214 Tutty, D. (1993) Determination of the Viscosity of Terrazole Technical: Lab Project Number: GRL-10337: GRL-FR-10337: 9258. Unpublished study prepared by Uniroyal Chemical Ltd. Research Labs. 12 p.

42954701 Pierce, J. (1992) Terrazole: Product Identity and Composition: Lab Project Number: 92205. Unpublished study prepared by Uniroyal Chemical Co., Inc. 3 p.

43232001 Riggs, A. (1994) Determination of the Storage Stability of Technical Terrazole: Lab Project Number: 9257. Unpublished study prepared by Uniroyal Chemical Ltd. 33 p.

43232002 Riggs, A. (1994) Determination of the Corrosion Characteristics of Commercial Packaging Materials For Terrazole Technical: Lab Project Number: 9267. Unpublished study prepared by Uniroyal Chemical Ltd. 18 p.

43597401 Pierce, J. (1995) Etridiazole: Explanation of Certified Limits and Confidential Statement of Formula: Lab Project Number: 9249. Unpublished study prepared by Uniroyal Chemical Co., Inc. 20 p.

Case No. 0009
Chemical No. 084701

Case Name: Terrazole
Registrant: Uniroyal Chemical Company, Inc.
Product(s): 98.6% T (EPA Reg. No. 400-413)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	42912204 ³ , 42954701 ³ , CSF 3/6/95 ⁴
830.1600	Description of materials used to produce the product	Y	00001553 , 42912201 ³
830.1620	Description of production process	Y	00001553 , 42912201 ³
830.1670	Discussion of formation of impurities	Y	42912202 ³
830.1700	Preliminary analysis	Y	00158120 , 42912203 ³ , 43597401 ⁴
830.1750	Certified limits	Y	42912204 ³ , CSF 3/6/95 ⁴
830.1800	Enforcement analytical method	Y	00158120 , 42912203 ³ , 43597401 ⁴
830.6302	Color	Y	00001553
830.6303	Physical state	Y	00001553
830.6304	Odor	Y	00001553
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	00001553 , 42912210 ³ , 42912211 ³ , 42912212 ³
830.6314	Oxidation/reduction: chemical incompatibility	Y	42912213 ³
830.6315	Flammability	Y	00001553
830.6316	Explosibility	Y	00062469
830.6317	Storage stability	Y	00001553 , 43232001 ⁵
830.6319	Miscibility	Y	00062469
830.6320	Corrosion characteristics	Y	00001553 , 43232002 ⁵
830.7000	pH	Y	00001553
830.7050	UV/Visible absorption	N ⁶	
830.7100	Viscosity	Y	42912214 ³
830.7200	Melting point/melting range	N/A ⁷	
830.7220	Boiling point/boiling range	Y	00001553
830.7300	Density/relative density/bulk density	Y	00001553
830.7370	Dissociation constants in water	Y	42912209 ³
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	42515901 ⁸
830.7840	Water solubility: column elution method; shake flask method	Y	00001553 , 00001644 , 42912205 ³ , 42912206 ³ , 42912207 ³
830.7950	Vapor pressure	Y	00001553 , 42912208 ³

¹ Y = Yes; N = No; N/A = Not Applicable.

² **Bolded** references were reviewed under the Terrazole (SRR) Reregistration Standard dated 3/30/89; and all other references were reviewed as noted.

³ CBRS No. 12714, D195979, 3/18/94, K. Dockter.

⁴ CBRS No. 15417, D213928, 5/8/95, K. Dockter.

⁵ CBRS No. 13768, D203660, 6/22/94, K. Dockter.

⁶ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

⁷ Data are not required because the T/TGAI is a liquid at room temperature.

⁸ CBRS No. 10875, D184741, 1/8/93, F. Toghrol.

ETRIDIAZOLE (TERRAZOLE)

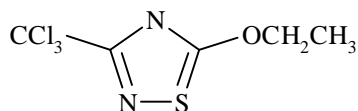
REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 084701; Case 0009

TABLE OF CONTENTS	page
INTRODUCTION	1
REGULATORY BACKGROUND	1
SUMMARY OF SCIENCE FINDINGS	2
OPPTS GLN 860.1200: Directions for Use	2
OPPTS GLN 860.1300: Nature of the Residue in Plants	4
OPPTS GLN 860.1300: Nature of the Residue in Livestock	4
OPPTS GLN 860.1340: Residue Analytical Methods	5
OPPTS GLN 860.1360: Multiresidue Method Testing	6
OPPTS GLN 860.1380: Storage Stability Data	6
OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants	7
OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed	8
OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	8
OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops	10
OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments	10
OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops	11
OPPTS GLN 860.1900: Field Accumulation in Rotational Crops	11
Tolerances Listed Under 40 CFR §180.370:	17
Tolerances Needed Under 40 CFR §180.370	18
DIETARY EXPOSURE ASSESSMENT SUMMARY	20
CODEX HARMONIZATION	20
AGENCY MEMORANDA	21
RESIDUE CHEMISTRY CITATIONS	23

ETRIDIAZOLE (TERRAZOLE)



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 084701; Case 0009

INTRODUCTION

Etridiazole [5-ethoxy-3-trichloromethyl-1, 2, 4-thiadiazole] is an organic, non-phytotoxic soil fungicide which is used to control various species of Pythium, Phytophthora, Fusarium, Rhizoctonia, damp off, and root and stem rots. Etridiazole is manufactured by Uniroyal Chemical Company, Inc., the basic producer, and its subsidiary, Gustafson, Inc., under the trade name Terrazole®. It is a reddish-brown liquid which is formulated as dusts (2.5% to 5% a.i.), granules (1.5% to 5% a.i.), wettable powders (35% a.i.), flowable concentrates (5.8% to 44.7% a.i.) and emulsifiable concentrates (4.3% to 44.3% a.i.). Tolerances are established for the residues of etridiazole and its monoacid metabolite [3-carboxy-5-ethoxy-1,2,4-thiadiazole] in or on the following raw agricultural commodities: avocados, corn, cottonseed, tomatoes, wheat, strawberries, meat, milk, poultry, and eggs (40CFR ' 180.370). Current uses include seed treatments, cotton (as an at-planting soil treatment), turf (limited to golf courses) and ornamentals. Etridiazole is registered for use on ten crops as a seed treatment (barley, beans, corn, cotton, peanuts, peas, sorghum, soybeans, safflower, and wheat). There are no registered homeowner uses.

REGULATORY BACKGROUND

Etridiazole is a List A reregistration chemical and was the subject of a Registration Standard and Second Round Review (SRR) dated 9/80 and 3/30/89, respectively. A Data Call-In (DCI) Notice for etridiazole was also issued 6/30/92. These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the SRR was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of etridiazole.

Tolerances for residues of etridiazole and its monoacid metabolite, 3-carboxy-5-ethoxy-1,2,4,-thiadiazole, in/on raw agricultural commodities (RACs) have been established under 40 CFR §180.370 . These tolerances range from 0.05 ppm in/on corn and wheat grain to 0.2 ppm in/on

cottonseed and strawberries. Tolerances have also been established for residues in eggs and milk at 0.05 ppm, and in fat, meat, and meat byproducts (mbyp) of poultry, cattle, goats, hogs, horses, and sheep at 0.1 ppm. No tolerances for residues of etridiazole have been established for processed commodities.

The qualitative nature of the residue in plants and animals is adequately understood based on acceptable cotton, soybean, and wheat metabolism studies, and poultry and ruminant metabolism studies. The Metabolism Assessment Review Committee (MARC) (D255738, D.Drew/M.Centra, 11/3/99) concluded that the etridiazole residues to be regulated in plant and animal commodities are etridiazole and its monoacid metabolite.

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 4/14/99 indicates that there are eleven etridiazole end-use products (EPs) with food/feed uses registered to Uniroyal and its subsidiary. Ten of the products (shown below) contain multiple active ingredients.

Etridiazole End-Use Products with Food/Feed Uses Registered to Uniroyal.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name	Additional Active Ingredients
400-405	3/97	0.5 lb/gal EC	TERRACLOR SUPER X Emulsifiable	PCNB (2 lb/gal EC)
400-406	3/98	2.5% G	TERRACLOR SUPER X Granular	PCNB (10% G)
400-408	12/96	1.53% G	TERRACLOR SUPER X With Di-Syston	PCNB (6.5% G) and disulfoton (6.5%)
400-422	1/98	4 lb/gal EC	TERRAZOLE 4EC	
400-455	6/95	0.5 lb/gal FIC	TERRACLOR SUPER X Flowable	PCNB (2 lb/gal FIC)
400-456	12/96	3.8% G	TERRACLOR SUPER X 18.8G	PCNB (15.0% G)
400-475	1/97	0.4 lb/gal EC	TERRACLOR SUPER X Plus Di-Syston	PCNB (1.5 lb/gal EC) and disulfoton (1.5 lb/gal EC)
7501-54	11/96	5% D	TERRACLOR SUPER X 20-5 Dust With Graphite	PCNB (20% G)
7501-57	11/96	0.5 lb/gal EC	TERRA-COAT L-205N Seed Treatment Fungicide with Dye	PCNB (2 lb/gal EC)
7501-111	5/95	2.5% D	4-WAY For Seed Disease Control Seed Protectant Fungicide	Captan (18% G), Maneb (18.75% G), PCNB (10% G)
7501-153	5/95	2.5% D	4-WAY Peanut Seed Protectant Fungicide	Captan (18% G), Maneb (18.75% G), PCNB (10% G)

A review of the labels listed above and supporting residue data indicate that the following label amendments are required:

Use directions on all labels permitting an in-furrow application to cotton should be amended to prohibit the use on cotton seed previously treated with etridiazole.

Use directions on all labels permitting seed treatment applications should be amended to stipulate the requirement to dye the treated seeds with an EPA-approved dye unless treated seed meets the requirement exemptions outlined in 40CFR 153.155.

Use directions on all labels permitting seed treatment applications should be amended to prohibit the use of treated seed for food, feed, or oil purposes.

All EP labels should be amended to specify the rotational crop restrictions delineated by the confined rotational crop study. Although the etridiazole rotational crop study indicated a 120-day plant-back interval (PBI) is needed for root crops, the Gustafson labels for EPs used as seed treatments (7501-54, -57, -111, and -153) should be amended to specify a 12-month PBI for root crops owing to the requirements for the PCNB active ingredient; the labels allowing at-planting in-furrow uses on cotton already specify a 12-month PBI for root crops on account of PCNB. A 30-day PBI should be established for leafy vegetables, small grains, and other rotated crops. Alternatively, if the registrant desires shorter plantback intervals, limited crop field trials should be conducted according to OPPTS Test Guidelines 860.1900.

A comprehensive summary of the registered food/feed use patterns of etridiazole, based on the product labels registered to Uniroyal and Gustafson, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of etridiazole is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of etridiazole food/feed uses are based on the use patterns registered by the basic producers, Uniroyal and Gustafson. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on cotton, soybean, and wheat metabolism studies. The currently regulated residues of concern are etridiazole and its monoacid metabolite, 3-carboxy-5-ethoxy-1,2,4,-thiadiazole. The MARC has concluded (DP Barcode D255738, D. Drew/M.Centra, 11/3/99) that the residues of concern in plants consist of etridiazole and its monoacid metabolite.

In the wheat metabolism study, parent compound was nondetectable in wheat grain, forage and straw grown from seed treated with [¹⁴C]etridiazole at 10x the registered rate. Neither parent etridiazole or its monoacid metabolite were found in wheat grain treated at the 10x rate. The major metabolite groups identified in wheat forage were 3-carboxy-5-hydroxyethoxy etridiazole (31.0% TRR, 0.45 ppm); combined residues of the monoacid and 3-hydroxymethyl-etridiazole (20.8% TRR, 0.30 ppm); and glucosides of 3-hydroxymethyl-etridiazole (10.0% TRR, 0.14 ppm). The major metabolite groups identified in wheat straw were 3-carboxy-5-hydroxyethoxy etridiazole (47.2% TRR, 1.94 ppm); combined residues of the monoacid and 3-hydroxymethyl-etridiazole (10.7% TRR, 0.44 ppm combined); and glucosides of 3-hydroxymethyl-etridiazole (13.7% TRR, 0.56 ppm). Natural constituents such as glycolic, malonyl oxamic, and oxalic acids accounted for 12.8-20.5% of the TRR in forage and straw and all of the ¹⁴C-activity identified, 84.8% of the TRR, in grain.

In the cotton metabolism study, parent compound and related metabolites were nondetectable in cottonseed or foliage grown in soil treated with [¹⁴C]etridiazole at the 100x rate and harvested at maturity 5 months after planting. Similar results were observed in soybean immature plants and seed harvested 30-45 days (forage and hay) and ~3 months (seed) after seed treatment with [¹⁴C]etridiazole at 10x. Etridiazole in soybean seed and forage was extensively degraded and the major components of the ¹⁴C-activity identified as endogenous biomolecules.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The current tolerance expression includes etridiazole and the monoacid. The MARC (D255738, D. Drew/M. Centra, 11/3/99) has determined that etridiazole and its monoacid metabolite are the residues of concern to be regulated in animal commodities.

The available poultry and ruminant metabolism studies indicate that etridiazole is extensively degraded, mainly to non-thiadiazole ring containing natural components; parent compound was not identified in any animal tissue, eggs or milk. No ring-containing metabolites were identified in any animal tissue, eggs or milk with the exception of the monoacid in goat liver (0.002 ppm normalized to 1x maximum theoretical dietary burden) and in hen liver (0.0001 ppm- 0.0002 ppm normalized to 1x maximum theoretical dietary burden).

In the hen metabolism study conducted at a feeding level of 50 ppm for 6 days (500x the maximum theoretical dietary burden for poultry, total ¹⁴C-residues (TRR) were 5.32-8.46 ppm in liver, 1.41-3.49 ppm in fat and muscle, and 0.023-1.52 ppm in eggs (residues had not plateaued in eggs by day 6); the only ring-containing metabolite identified was the monoacid which accounted for 1-2% of the TRR (0.05-0.08 ppm) in liver and was nondetectable in eggs.

After 6 days of feeding at 50 ppm of [¹⁴C]etridiazole (172x the maximum theoretical dietary burden for dairy cattle) TRR were 12.6-17.6 ppm in goat liver, 0.17-5.74 ppm in kidney, muscle, and fat, and up to 0.464 ppm in milk. No thiadiazole ring-containing metabolites were identified in milk or tissues with the exception of the monoacid accounting for ~2% (0.35 ppm) of the TRR in liver.

OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of etridiazole, as currently defined, on animal and plant commodities.

The Pesticide Analytical Manual (PAM) Vol. II describes a GC/ECD method for determining etridiazole *per se* (Method I), and a HPLC/UV method for determining the monoacid metabolite (Method A), each in/on plant commodities (avocado, cottonseed, and strawberries). The reported sensitivity of the methods for residues of etridiazole and the monoacid is 0.05 ppm for each analyte. PAM Volume II does not describe any methods for enforcing tolerances for residues in animal commodities; however, the Etridiazole SRR (3/30/89) indicates that two Agency validated methods are available for tolerance enforcement, a GC/ECD method entitled, "Determination of Residues of Terrazole in Chicken Matrices," capable of quantitating etridiazole *per se* in eggs and beef liver, and a HPLC method (CAM-47-81) that determines the monoacid in eggs and beef liver. These methods should be included in future updates of PAM Volume II.

Residue data on crop and animal commodities have been collected using the above GC/ECD and HPLC methods with only minor modifications involving changes in solvents and cleanup procedures.

OPPTS GLN 860.1360: Multiresidue Method Testing

The registrant has submitted multiresidue testing data (MRID 43259601) for etridiazole and its monoacid metabolite using FDA multiresidue Protocols B, C, D, and E; Protocol A was not used as the analytes do not possess the N-methylcarbamate moiety. These data have been forwarded to FDA (DP Barcode D205025, L. Edwards, 7/24/94). The FDA PESTDATA database (PAM Volume I, Appendix I, 3rd edition, 1994) indicates that etridiazole is completely recovered (>80%) by Multiresidue Protocol D and E (PAM I Sections 232.4 and 211.1), and partially recovered (50-80%) by Multiresidue Protocol E (PAM I Section 212.1). Recovery data for the monoacid metabolite were not reported in this edition of PAM I.

OPPTS GLN 860.1380: Storage Stability Data

The requirements for supporting storage stability data for etridiazole residues in plant commodities are satisfied for the purposes of reregistration. The available storage stability data indicate that residues of etridiazole *per se* and the monoacid are stable in frozen cottonseed for up to 12 months. These data adequately support the cotton residue field trial in which samples of cottonseed and gin trash were analyzed within ~1 year of collection. Processed fractions were not analyzed as residues were non-quantifiable in the RAC after 6x treatment.

The metabolism studies conducted on cotton, soybean, and wheat to support seed treatment uses on barley, beans, corn, cotton, peas, peanuts, safflower, sorghum, soybeans, and wheat are adequately supported by storage stability data indicating that [¹⁴C]etridiazole residues were stable in frozen samples and extracts for the duration of these studies.

The requirements for storage stability data on animal commodities are not satisfied for the purposes of reregistration. Data are required depicting the storage stability of the monoacid metabolite stored frozen in animal commodities for up to 2 years. Samples from the poultry and ruminant feeding studies were stored frozen for ~6 weeks and 2 years, respectively, prior to analysis for residues of the monoacid.

The available storage stability data indicate that etridiazole *per se* is stable in poultry muscle, fat, skin, and eggs stored at -20 C for up to 6 weeks, the approximate period of frozen storage for samples in the poultry feeding study, etridiazole is not stable in frozen giblets (pooled liver, heart, and gizzard). Etridiazole *per se* was also shown to be stable in goat liver stored at -20 C for ~1 week, but declined by ~50% after 7 months of frozen storage. These data support the poultry feeding study with respect to etridiazole *per se*. As samples from the ruminant feeding study were analyzed for residues of parent compound within one month of collection, no additional data are required depicting the storage stability of etridiazole *per se* in cow tissues and milk.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

For purposes of reregistration, the requirements for magnitude of the residue data in/on plants are fulfilled for the in-furrow application to cotton and are waived for the seed treatment uses on barley, beans, corn, cotton, peanuts, peas, sorghum, safflower, and wheat.

In addition to the metabolism study demonstrating that residues of parent and the monoacid are non-detectable in cottonseed or foliage harvested at maturity after treatment at 100x, adequate residue data are available to reassess the current tolerance for residues in/on undelinted cottonseed. Residues of etridiazole *per se* were <0.005 ppm (<LOQ) in/on four samples of cottonseed harvested 138-145 days after in-furrow at-planting treatment with etridiazole (2.5% G) at 1.8 lb ai/A, 6x the maximum seasonal rate (DP Barcode D244960, S. Law and D. Soderberg, 1/19/99). Data from older studies (E. Zager memo dated 2/1/82) also suggest that quantifiable residues are unlikely in cotton treated with etridiazole according to the current use pattern. In ten trials conducted in five states, cotton was treated with etridiazole (4 lb/gal EC) at-planting at 0.5-1.0 lb ai/A (1.3-2.6x rate) or postemergence (2-4 leaf stage) at 0.25 lb ai/A, and residues of etridiazole were <0.02 (<LOQ) in the majority of the samples analyzed; only one sample treated at planting at the 1.3x rate bore detectable residues of etridiazole *per se* at 0.06 ppm. Residues of the monoacid were <0.05 ppm (<LOQ) in/on all samples analyzed. The available data suggest that a tolerance at the combined LOQs is appropriate for residues of etridiazole in/on cottonseed.

Cotton gin byproducts are now considered a significant livestock feed item (OPPTS.GLN 860.1000, Table 1). HED has previously concluded (DP Barcode D244960, S. Law/D. Soderberg, 1/19/99) that residue data provided from two tests on cotton gin byproducts derived from cotton grown from seed treated at 6x partially satisfies the requirement for data on cotton gin byproducts. As data from the cotton processing and metabolism study conducted at exaggerated rates indicate that etridiazole residues are unlikely to be quantifiable in gin trash, additional data on cotton gin byproducts are not required. The available data indicate that a tolerance at the combined LOQs is needed for residues of etridiazole in/on cotton gin byproducts.

The Etridiazole SRR (3/89) required radio tracer uptake studies to support etridiazole seed treatment uses on barley, beans, peanuts, peas, safflower, soybean, and sorghum because no residue data were available to support these uses. At that time, no tolerances were established for these commodities because seed treatment uses were considered non-food uses. [Note: Tolerances were established for residues of etridiazole in/on corn and wheat commodities because the use patterns on these crops allowed pre-plant, at-planting, or postemergence treatments in addition to seed treatments. Currently, the registrant is supporting only seed treatment use on corn and wheat.] As detectable ¹⁴C-activity was expected in the aerial portions of these crops as a result of seed treatment, the registrant proposed conducting metabolism studies designed to provide sufficient radioactivity in the mature crop to permit residue characterization and identification (P Deschamp, 1/22/93). HED concurred (DP Barcode D188371, P. Deschamp, 3/4/93) and required metabolism studies on soybeans and wheat conducted at exaggerated rates

to support reregistration of etridiazole seed treatments.

In the metabolism studies, etridiazole *per se* was non-detectable in/on all cotton, soybean, and wheat matrices analyzed. However, residues of the monoacid were detected as a component of ¹⁴C-residues in wheat forage (20.8% TRR, 0.30 ppm) and straw (10.7% TRR, 0.44 ppm) treated at 10x. In addition, residues of the monoacid accounted for 4% of the TRR (0.033 ppm) in rotational wheat forage grown at the 30-day PBI in soil treated with [¹⁴C]etridiazole at ~1x rate. These data indicate that residues of the monoacid would not be expected to exceed 0.04 ppm in wheat forage and straw grown from seed treated at 1x. Based on these results, appropriate tolerances for residues of etridiazole in/on commodities grown from etridiazole treated seed should be set at the combined LOQ (0.1 ppm) of the available enforcement methods for etridiazole and the monoacid.

Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown outside of the United States in order to reassess a tolerance for tomatoes. In the absence of such data, the current tolerance for tomatoes will be revoked as the registrant is no longer supporting use on domestic tomatoes.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for cottonseed. Residues of etridiazole *per se* were <0.005 ppm (<LOQ) in/on cottonseed grown from seed treated at 6x the registered rate; as no quantifiable residues were found in the RAC samples, cottonseed processed fractions were not analyzed. The registrant did not analyze for the monoacid; however, as residues of the monoacid were nondetectable in cottonseed from the 100x metabolism study, additional data on the metabolite in cottonseed processed commodities are not required.

In addition, the requirement for magnitude of the residue in processed food/feed commodities is considered fulfilled for seed treatment uses on crops with processed commodities (barley, corn, peanuts, safflower, sorghum, soybean, and wheat). As residues of etridiazole and the monoacid were nondetectable in soybean seed and wheat grain from the exaggerated rate (10x) soybean and wheat metabolism studies, processing studies or tolerances are not required for processed fractions of barley, corn, peanuts, sorghum, safflower, soybean, and wheat.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Provided that storage stability issues are resolved, the reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are satisfied. Based upon the established tolerances for etridiazole residues in/on animal feed items, the calculated maximum theoretical dietary burdens for livestock are presented below:

Calculation of maximum dietary burdens ('worse case') of livestock animals for etridiazole.

Feed Commodity	% Dry Matter ^a	% Diet ^a	Tolerance (ppm) ^b	Dietary Contribution (ppm) ^c
Beef Cattle				
corn grain	88	60	0.1	0.07
corn forage	40	40	0.1	0.10
TOTAL BURDEN		100		0.17
Dairy Cattle				
wheat forage	25	60	0.1	0.24
sorghum grain	86	40	0.1	0.05
TOTAL BURDEN		100		0.29
Poultry				
corn grain	N/A	80	0.1	0.08
corn milled products	N/A	20	0.1 ^d	0.02
TOTAL BURDEN		100		0.10
Swine				
corn grain	N/A	80	0.1	0.08
corn milled products	N/A	20	0.1 ^d	0.02
TOTAL BURDEN		100		0.10

^a OPPTS 860 Guidelines Table 1 (August 1996).

^b Current or reassessed tolerance from Table C.

^c Contribution = [tolerance / % DM (if cattle)] X % diet.

^d Based upon the 0.1 ppm tolerance for residues in/on corn grain.

In the ruminant feeding study conducted at feeding levels of 0.1, 1.0, and 10.0 ppm (0.3x, 3.4x, and 34.5x the dietary burden for dairy cattle), residues of etridiazole *per se* and the monoacid were non-detectable (each <0.05 ppm) in muscle, kidney, and liver at all dose levels. Fat samples from two high-dose cows bore residues of etridiazole *per se* at 0.04 and 0.12 ppm. Fat samples were not analyzed for the monoacid (residues of the metabolite were not expected in fat due to its solubility in water). Residues of etridiazole *per se* were non-detectable (<0.01 ppm) in milk samples with the exception of a few samples, at all dose levels, bearing trace amounts at 0.01 ppm. Residues of the monoacid were <0.05 ppm in milk samples from the 10.0 ppm feeding level. In a separate study on one cow fed at 1000 ppm (3450x) for 3 days, residues of the monoacid were 0.08 ppm in milk and non-detectable in muscle, liver, and kidney.

In the poultry feeding study, hens were dosed with etridiazole at 0.1, 1.0 or 10.0 ppm (1x, 10x, and 100x the dietary burden for poultry). At the 10 ppm dose (100x), residue levels of etridiazole *per se* and the monoacid were each <0.1 ppm (<LOQ) in meat, fat, skin, giblets (pooled liver, heart, and gizzard), and <0.01 and <0.05 ppm, respectively, in eggs (<LOQ). [The available storage stability data indicate that residues of etridiazole *per se* in giblets decline by 78% after 6 weeks of frozen storage, the storage interval for giblet samples from the feeding study; however, data from the poultry metabolism study indicate that residues of etridiazole and the monoacid

would not exceed 0.1 ppm in liver at the 500x feeding level].

These data indicate that a Category 6(a)(3) {40CFR 180.6(a)3 “no reasonable expectation of finite residues”} situation exists with respect to residues of etridiazole and the monoacid metabolite in meat, mbyp (meat by-products), fat, and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, mbyp, and eggs. Therefore, at this time, tolerances for etridiazole in animal commodities will be revoked. However, once the outstanding storage stability data on the monoacid metabolite is submitted and reviewed, the 6(a)3 status may be reevaluated. Additionally, if the current etridiazole use patterns change, it will be necessary to reevaluate the 6(a)3 status.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

Etridiazole is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Etridiazole is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

An adequate confined rotational crop study has been submitted. Radioactive residues in rotational crops grown in [¹⁴C]etridiazole-treated (0.413 lb ai/A, ~1x) soil were adequately identified/characterized. The metabolic profile of etridiazole in rotational crops is qualitatively similar to the profile elucidated in primary crops.

At the 30-day PBI, no parent compound was found in any of the rotational crop matrices analyzed, and minor amounts of the monoacid were found in wheat forage (4% TRR, 0.033 ppm[monoacid plus other compounds which are not of toxicological concern]). The principle residues identified were metabolites grouped by the registrant under the designation AFI@ accounting for 12-47% of the TRR and including 2-imino-3-(β-D-glucopyranosyl) propanoic acid; 3-[3-(1,2,4-thiadiazolyl)]-2-propanoic acid; 3-(acetylamino)-3-oxopropanoic acid; glycolic acid; glycine; and acetamide. Major components of the residue also included the 3-carboxy-5-hydroxyethoxy etridiazole metabolite (7-38% TRR), and group AF4a@metabolites including 3-hydroxymethyl etridiazole conjugates and 3-carboxy- etridiazole methylester (<3-36% TRR). Minor amounts of 3-hydroxymethyl etridiazole and its reduced form (<1-8% TRR) were found.

In turnips at the 30-day PBI, TRR were 0.18-2.38 ppm; parent and the monoacid metabolite were nondetectable (<0.005 ppm). At the 120-day PBI, TRR were 0.013-0.017 ppm in turnip tops (immature) and wheat forage and straw, and <0.01 ppm in mature turnip tops and roots and wheat grain; however, no parent compound or metabolites of etridiazole were identified above 0.005 ppm in any matrix at this interval. At the 365 day PBI, TRR in turnips and wheat did not exceed 0.01 ppm.

At the 30 day PBI, TRR were 0.054 ppm in mature lettuce. At the 120 day PBI, TRR in lettuce did not exceed the trigger value of 0.01 ppm. Residues of etridiazole and the monoacid were nondetectable (<0.005 ppm) in lettuce.

Based on these results, rotational crop restrictions should be established at 30 days for leafy vegetables and 120 days for root crops, small grains and other rotated crops. However, owing to the requirements for the PCNB active ingredient, Gustafson seed treatment EP labels (7501-54, -57, -111, and -153) should be amended to specify a 12-month PBI for root crops; the labels allowing at-planting in-furrow uses on cotton already specify a 12-month PBI for root crops on account of PCNB. No tolerances for inadvertent residues of etridiazole are required for these crop groups when planted at the appropriate plantback interval.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops:

Limited field studies are not required provided that all EP labels are amended to reflect the PBIs suggested by the the results of the confined study discussed above. Alternatively, if the registrant desires shorter plantback intervals, limited crop field trials should be conducted (OPPTS Test Guidelines 860.1900).

Table A. Food/Feed Use Patterns Subject To Reregistration for Etridiazole (Case 0009).

Site Application Type Application Timing	Formulation [EPA Reg. No.]	Max. Single Application Rate ^a	Use Limitations ^b
Barley, Peas, and Soybean			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.20-0.25 oz ai/bushel seed	
Beans			
Seed treatment	5% D [7501-54]	0.1 oz ai/bushel seed	
	0.5 lb/gal EC [7501-57]	0.125 oz ai/100 lbs seed	
Corn and Sorghum			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.1-0.125 oz ai/100 lbs seed	
Cotton			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.80-1.0 oz ai/100 lbs seed	
In-furrow At-planting	1.53% G [400-408] 2.5% G [400-406] 3.8% G [400-456] 0.4 lb/gal EC [400-475] 0.5 lb/gal EC [400-405] 0.5 lb/gal FIC [400-455]	0.23-0.38 lb ai/A	Apply only at planting. The labels prohibit the feeding or grazing of cotton foliage by livestock, and specify a 12-month plantback interval for <u>root crops</u> unless PCNB is registered for use on these crops. Applications of the EC and FIC formulations are made in 5-15 gal/A of water.
Peanuts			
Seed treatment	2.5% D [7501-111] [7501-153] 5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.15-0.25 oz ai/100 lbs seed	
Safflower			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-54]	0.2-0.25 oz ai/100 lbs seed	
Wheat			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.1-0.125 oz ai/bushel seed	

^a A maximum of one application/season is implied by the labeled use pattern.

^b Labels allowing seed treatment uses prohibit the use of treated seed for food, feed, or oil purposes and require that the treated seed be dyed.

Table B. Residue Chemistry Science Assessments for Reregistration of Etridiazole.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A	Yes ²	See Table A.
860.1300: Plant Metabolism	N/A	No	00001689 00028419 00093751 43940001 ³ 44054701 ⁴ 44285201 ⁵ 44453201 ⁶
860.1300: Animal Metabolism	N/A	No	00093753 00093754
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00001570 00001645 00002229 00002239 00002257 00028423 00028424 00028428 00014333 00093752 00139669
- Animal commodities	N/A	No	00001695 00093752 00093755
860.1360: Multiresidue Methods	N/A	No	43259601 ⁷
860.1380: Storage Stability Data	N/A	Yes ⁸	00093754 00093755 44285001 ⁹ 43305701 ¹⁰
860.1500: Crop Field Trials			
<u>Legume Vegetables (Succulent or Dried)</u>			
- Beans	None	No ¹¹	
- Peas	None	No ¹¹	
- Soybean, seed	None	No ¹¹	
<u>Foliage of Legume Vegetables</u>			
- Soybean, forage and hay	None	No ¹¹	
<u>Fruiting Vegetables</u>			
- Tomato	0.15 [§180.370]	Yes ¹²	
<u>Cereal Grains Group</u>			
- Barley, grain	None	No ¹¹	
- Corn, field, grain	0.05 [§180.370]	No ¹¹	
- Sorghum, grain	None	No ¹¹	
- Wheat, grain	0.05 [§180.370]	No ¹¹	
<u>Forage, Fodder and Straw of Cereal Grains</u>			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Barley, hay and straw	None	No ¹¹	
- Corn, fodder and forage	0.1 [§180.370]	No ¹¹	
- Sorghum, forage and stover	None	No ¹¹	
- Wheat, forage and straw	0.1 [§180.370]	No ¹¹	
- Wheat, hay	None	No ¹¹	
<u>Miscellaneous Commodities</u>			
- Cottonseed	0.2 [§180.370]	No	00014318 00028427 00064191 00064194 44285901 ¹⁴
- Cotton gin by products	None	No	44285901 ¹⁴
- Peanut, nutmeat and hay	None	No ¹¹	
- Safflower	None	No ¹¹	
- Strawberries	0.2 [§180.370]	No ¹³	
860.1520: Processed Food/Feed			
- Barley, corn, peanut, safflower, soybean, and wheat	None	No ¹⁵	
- Cottonseed	None	No	44285901 ¹⁴
860.1480: Meat, Milk, Poultry, and Eggs			
- Eggs	0.05 [§180.370]	No	00093755 00093756
- Milk	0.05 [§180.370]	No	00093747 00093748
- Poultry fat, mby, and meat	0.1 [§180.370]	No	00093755 00093756
- Cattle, goats, hogs, horses, and sheep fat, mby, and meat	0.1 [§180.370]	No	00093747 00093748
860.1400: Water Fish and Irrigated Crops			
860.1460: Food Handling			
860.1850: Confined Rotational Crops			
860.1900: Field Rotational Crops	None	Yes ¹⁷	44311401 ¹⁶

1. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Etridiazole Reregistration Standard dated 9/80, and *italicized* references were reviewed or summarized in the Residue Chemistry Chapter of the Etridiazole Second Round Review (SRR) dated 3/30/89. All other references were reviewed as noted.
2. Use directions on all labels permitting an in-furrow application to cotton should be amended to prohibit the use on cotton seed previously treated with etridiazole.

Use directions on all labels permitting seed treatment applications should be amended to stipulate the requirement to dye the treated seeds with an EPA-approved dye unless treated seed meets the requirement exemptions outlined in 40CFR 153.155.

Use directions on all labels permitting seed treatment applications should be amended to prohibit the use of treated seed for food, feed, or oil purposes.

All EP labels should be amended to specify the rotational crop restrictions delineated by the confined rotational crop study. Although the etridiazole rotational crop study indicated a 120-day plant-back interval (PBI) is needed for root crops, the Gustafson labels for EPs used as seed treatments (7501-54, -57, -111, and -153) should be amended to specify a 12-month PBI for root crops owing to the requirements for the PCNB active ingredient; the labels allowing at-planting in-furrow uses on cotton already specify a 12-month PBI for root crops on account of PCNB. A 30-day PBI should be established for leafy vegetables, small grains, and other rotated crops. Alternatively, if the registrant desires shorter plantback intervals, limited crop field trials should be conducted according to OPPTS Test Guidelines 860.1900.
3. DP Barcode D224428, D. Hrды, 11/14/97
4. DP Barcode D228163, D. Hrды, 5/30/97
5. DP Barcode D244973, D. Drew, 10/29/98
6. DP Barcode D244975, S. Law, 9/29/98
7. DP Barcode D205025, L. Edwards, 7/15/94
8. Data are required depicting the storage stability of the monoacid metabolite stored frozen in animal commodities for up to 2 years. Samples from the poultry and ruminant feeding studies were stored frozen for approximately 6 weeks and 2 years, respectively, prior to analysis for residues of the monoacid.
9. DP Barcode D244972, D Soderberg, 1/20/99
10. DP Barcode D255738, D. Drew/M.Centra, 11/3/99.
11. HED concluded (DP Barcode D188371, P. Deschamp, 3/4/93) that metabolism studies conducted at exaggerated rates on wheat and soybean would support seed treatment uses on barley, beans, corn, cotton, peanuts, peas, safflower, sorghum, soybeans, and wheat. Adequate metabolism studies on cotton, soybean, and wheat (DP Barcodes D224428, D228163, and D244973; D Hrды/D. Drew; 5/30/97, 11/14/97, and 10/29/98) support the residue data requirements for these seed treatment uses.
12. The registrant is no longer supporting uses on tomatoes grown domestically. In order to reassess a tolerance on tomatoes, additional field trial data reflecting etridiazole use on tomatoes grown outside the United States as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required.
13. The registrant is no longer supporting uses on strawberries.
14. DP Barcode D244960, S. Law/D. Soderberg, 1/19/99
15. As residues of etridiazole and the monoacid metabolite were nondetectable in soybean seed and wheat grain from the exaggerated rate (10x) soybean and wheat metabolism studies, processing studies and tolerances

are not required for the processed fractions of barley, corn, peanuts, safflower, sorghum, soybeans and wheat.

16. DP Barcode D244963, D. Drew, 12/3/98
17. If the registrant wants shorter PBIs than those recommended by the Agency in the review of the confined rotational crop study, limited field trial data are required.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of etridiazole are currently expressed in terms of etridiazole and its monoacid metabolite under 40 CFR §180.370. The MARC has concluded (D255738, D. Drew/M.Centra, 11/3/99) that the residues of concern in plant and animal commodities include etridiazole and its monoacid metabolite. A summary of the etridiazole tolerance reassessment for crops and livestock commodities and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.370:

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for etridiazole residues in/on undelinted cottonseed. Based upon the current use patterns and the available residue data, the established tolerances for etridiazole residues in/on undelinted cottonseed can be lowered to 0.1 ppm.

Sufficient data are also available to reassess the tolerances for residues in/on corn and wheat commodities. The tolerances for residues of etridiazole in/on corn and wheat grain at 0.05 ppm should be reassessed at 0.1 ppm. The available residue data support the tolerances at 0.1 ppm for residues in/on corn forage and fodder and wheat forage and straw.

The tolerance for avocados and strawberries should be revoked as the registrant is no longer supporting those crops. Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown outside of the United States in order to reassess a tolerance for tomatoes. In the absence of such data, the current tolerance for tomatoes will be revoked as the registrant is no longer supporting use on domestically grown tomatoes.

Data indicate that a Category 6(a)(3) {40CFR 180.6(a)3 “no reasonable expectation of finite residues”} situation exists with respect to residues of etridiazole and the monoacid metabolite in meat, mby (meat by-products), fat, and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, mby, and eggs. Therefore, at this time, tolerances for etridiazole in animal commodities will be revoked. However, once the outstanding storage stability data on the monoacid metabolite is submitted and reviewed, the 6(a)3 status may be reevaluated. Additionally, if the current etridiazole use patterns change, it will be necessary to reevaluate the 6(a)3 status.

Tolerances Needed Under 40 CFR §180.370:

New tolerances are needed for etridiazole residues in/on the following RACs: cotton gin byproducts, peanut nutmeat and hay, sorghum grain and forage, barley grain and hay, and safflower seed. The available residue data indicate that tolerances for residues of etridiazole should be established on these commodities at 0.1 ppm.

In addition, new tolerances are needed for etridiazole residues in/on the following crop group: legume vegetables (succulent or dried) crop group and foliage of legume vegetables, each at 0.1 ppm.

Table C. Tolerance Reassessment Summary for Etridiazole

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.370:			
Avocados	0.15	Revoke	The registrant is no longer supporting use on avocados.
Corn, field, grain	0.05	0.1	Residue data indicate that the tolerance for residues in/on corn grain should be increased to 0.1 ppm.
Corn, fodder	0.1	0.1	
Corn, forage	0.1	0.1	
Cotton, seed	0.2	0.1	The available data support lowering the tolerance. <i>Cotton, undelinted seed</i>
Strawberries	0.2	Revoke	The registrant is no longer supporting use on strawberries.
Tomatoes	0.15	To Be Determined	The registrant is no longer supporting use on domestically grown tomatoes. Tolerance to be determined based on import residue field trial data.
Wheat, grain	0.05	0.1	Residue data indicate that the tolerance for residues in/on wheat grain should be increased to 0.1 ppm.
Wheat, forage	0.1	0.1	
Wheat, straw	0.1	0.1	
Eggs	0.05	Revoke	A Category 6(a)3 situation exists with respect to residues of etridiazole and the monoacid metabolite in livestock commodities.
Milk	0.05		
Fat, mbyp, and meat of poultry	0.10		
Fat of cattle, goats, hogs, horses, and sheep	0.10		
Meat and mbyp of cattle, goats, hogs, horses, & sheep	0.10		

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances needed under 40 CFR §180.370 (a)			
Cotton gin byproducts	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in <i>cotton gin byproducts</i> .
Foliage of legume vegetables crop group	None	0.1	Residue data support establishing a 0.1 ppm tolerance on the <i>foliage of legume vegetables</i> crop group.
Legume vegetables (succulent or dried) crop group	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in the <i>legume vegetables (succulent or dried)</i> crop group.
Barley, grain	None	0.1	Residue data support a 0.1 ppm tolerance.
Barley, hay	None	0.1	
Peanut, nutmeat	None	0.1	
Peanut, hay	None	0.1	
Safflower seed	None	0.1	
Sorghum, grain	None	0.1	
Sorghum, forage	None	0.1	

DIETARY EXPOSURE ASSESSMENT SUMMARY

For reregistration and risk assessment purposes, adequate plant and animal metabolism data are available. Adequate magnitude of the residue data or plant metabolism data on etridiazole residues are also available for all registered commodities. Adequate residue data are available to support the waiver of the requirement for processing studies and tolerances on processed commodities. A risk assessment for the uses of etridiazole can be conducted at this time using existing and reassessed tolerances. For tomatoes, the current tolerance of 0.15 ppm for domestically grown tomatoes will be used in the risk assessment. The risk assessment will be modified upon establishment of an import tolerance for tomatoes.

CODEX HARMONIZATION

There are currently no Codex Maximum Residue Limits (MRLs) established for residues of etridiazole in/on plant or animal commodities (electronic correspondence from S. Funk, 4/20/99).

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: None
Subject: January 14, 1993. Meeting with Representatives from Uniroyal Chemical Co. to Discuss Reregistration Data Requirements for Terrazole. Metabolism Studies for Seed Treatment Uses.
From: P. Deschamp
To: Chemistry Branch files
Dated: 1/22/93
MRID(s): None

DP Barcode: D188371
Subject: Reregistration of Etridiazole (Terrazole). Request for Time Extension: Plant Metabolism Studies in Support of Seed Treatment Uses.
From: P. Deschamp
To: S. Cerelli
Dated: 3/4/93
MRID(s): None

DP Barcode: D205025
Subject: Testing of Terrazole and Its Monoacid Metabolite through FDA Multiresidue Protocols B, C, D, and E.
From: L. Edwards
To: H. Hundley
Dated: 7/15/94
MRID(s): 43259601

DP Barcode: D228163
Subject: Terrazole® (Etridiazole). Nature of Residue in Wheat Grown from Treated Seeds.
From: D. Hrdy
To: M. Metzger
Dated: 5/30/97
MRID(s): 44054701

DP Barcode: D224428
Subject: Etridiazole (Terrazole®). Uniroyal Chemical Company, Inc. Data Call-in (DCI), Nature of Residue in Cotton (Soil Treatment).
From: D. Hrdy
To: S. Cerelli
Dated: 11/14/97
MRID(s): 43940001

DP Barcode: D244975
Subject: Etridiazole. Amendment: Metabolism of ¹⁴C-Etridiazole in Mature Cotton After Soil Treatment.
From: S. Law
To: M. Hartman
Dated: 9/29/98
MRID(s): 44453201

DP Barcode: D244973
Subject: Etridiazole (084701)(Terrazole®), Data Call-In, Nature of the Residue in Soybean as a Seed Treatment (860.1300).
From: D. Drew
To: M. Hartman
Dated: 10/29/98
MRID(s): 44285201

DP Barcode: D244963
Subject: Etridiazole (084701)(Terrazole®), Confined Accumulation in Rotational Crops: Lettuce, Turnip, and Wheat (860.1850).
From: D. Drew
To: M. Hartman
Dated: 12/3/98
MRID(s): 44311401

DP Barcode: D244960
Subject: Etridiazole: Magnitude of the Residue in Cottonseed, Cotton Gin Byproducts, and Cotton Processed Commodities.
From: S. Law
To: M. Hartman
Dated: 1/19/99
MRID(s): 44285901

DP Barcode: D244972
Subject: Etridiazole: Freezer Storage Stability of Etridiazole and the 3-Carboxylic Acid of Etridiazole in Cotton.
From: D. Soderberg
To: M. Hartman
Dated: 1/20/99
MRID(s): 44285001

DP Barcode: D255738
Subject: Etridiazole: Outcome of the 5/11/99 Meeting of the Metabolism Advisory Review Committee

From: M.Centra/D.Drew
To: George Kramer
Date: 11/3/99
MRID(s): None

RESIDUE CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

00001570 Griffith, W.P. (1973) Determination of Terrazole® (5-Ethoxy-3-Trichloromethyl-1,2,4-Thiadiazole) and Terraclor® (Penta-chloronitrobenzene) and Ald on unknown date under 9F0754; prechloronitrobenzene) and Allied Metabolites in Plant Tissues or Harvest Samples. Method CAM-24-73 dated Jul 3, 1973. (Unpublished study received Feb 4, 1977 under 1258-812; submitted by Olin Corp., Agricultural Div., Little Rock, Ark.; CDL:095799-M)

00001645 Griffith, W.P. (1975) Appendix: Determination of Terrazole® (5-Ethoxy-3-Trichloromethyl-1,2,4-Thiadiazole) in Avocado: CASR- 19-76. Method CAM-23-75 dated Jun 12, 1975. (Unpublished study received Oct 20, 1976 under 1258-812; submitted by Olin Corp., Agricultural Div., Little Rock, Ark.; CDL:228143-C)

00001689 McKennis, H., Jr.; Bowman, E.R. (1974) Studies on the Disposition and Metabolism of Terrazole-¹⁴C (3-Trichloromethyl-5-Ethoxy- 1,2,4-Thiadiazole) in Young 1,2,4-Thiadiazole) in Young Cotton Grown in Terrazole--¹⁴C - Treated Soil. (Unpublished study received Aug 20, 1971 under 0F0997; prepared by Medical College of Virginia, Dept. of Pharmacology, submitted by Olin Chemicals, Stamford, Conn.;CDL:091720-B)

00001695 Kuchar, E.J. (1971) Determination of 3-Carboxy-5-Ethoxy-1,2,4- Thiadiazole in Milk and Cow Tissue. Method CAM-10-71 dated Jul 16, 1971. (Unpublished study received Aug 20, 1971 under 0F0997; submitted by Olin Chemicals, Stamford, Conn.; CDL:091720-N)

00002229 Thomas, R.J. (1970) Determination of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole in Cotton Seeds: Analytical Method. Method CAM-10-70 (Tentative) dated Apr 15, 1970. (Unpublished study including letter dated May 21, 1971 from R.F. Philpitt to W.H. Morgan, received May 28, 1970 under 0F0997; submitted by Olin Corp., Stamford, Conn.; CDL:091717-AI)

00002239 Thomas, M.P. (1964) Determination of 5-Ethoxy-3-trichloromethyl-1, 2,4-thiadiazole (Olin 2424) and Pentachloronitrobenzene (PCNB, Olin 275) in Cottonseed. Method CAM-18-64 dated Jun 12, 1964. (Unpublished study received Dec 16, 1964 under 1258-740; submitted by Olin Mathieson Chemical Corp., New Haven, Conn.; CDL:119218-B)

00002257 Kuchar, E.J. (1971) Residues of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole in Cotton Seed: CASR-3-71. Includes method CAM-11-71 dated Jul 19, 1971. (Unpublished study received Jul

22, 1971 under 0F0997; submitted by Olin Corp., New Haven, Conn.; CDL:097541-A)

00014318 Olin Corporation (1971) Cotton Plants Grown in Terrazole (5-Ethoxy-3-trichloromethyl-1,2,4-thiadiazole) Treated Soil. (Unpublished study received on unknown date under 0F0997; CDL:098490-C)

00014333 Thomas, R.J.; Griffith, W.P. (1976) The Liquid Chromatographic Determination of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole in Straw-berries. Method CAM-16-76 dated Apr 20, 1976. (Unpublished study received Jul 6, 1979 under 1258-812; submitted by Olin Corp., Stamford, Conn.; CDL:238774-C)

00028419 Thomas, R.J.; Burger, R.N.; Iacoviello, S.A.; et al. (1978) Uptake and Tissue Retention of Terrazole® 14C (3-Trichloromethyl-5-ethoxy-1,2,4-thiadiazole) in Corn Grown in Soil Treated with Terrazole® 14C Coated Urea: Report No. 0446-78. Method CASR-15-78 dated Dec 11, 1978. (Unpublished study received Jan 23, 1980 under 1258-1003; submitted by Olin Corp., Stamford, Conn.; CDL:099210-B)

00028423 Iacoviello, S.A.; Burger, R.N.; Thomas, R.J. (1979) Determination of Terrazole® (3-Trichloromethyl-5-ethoxy-1,2,4-thiadiazole) and the Dichloro Metabolite (3-Dichloromethyl-5-ethoxy-1,2,4-thiadiazole) in Plant Tissue or Harvest Samples. Method CAM-12-79 dated Mar 5, 1979. (Unpublished study received Jan 23, CDL:099210-F)

00028424 Thomas, R.J.; Iacoviello, S.A. (1979) The Liquid Chromatographic Determination of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole in Plant Tissues or Harvest Samples. Method CAM-16-79 dated Mar 13, 1979. (Unpublished study received Jan 23, 1980 under 1258-1003; submitted by Olin Corp., Stamford, Conn.; CDL:099210-G)

00028427 Thomas, R.J.; Venezia, P.M.; Iacoviello, S.A. (1980) Residues of Terrazole®, Terraclor®, Impurities and Metabolites in Cotton Seed, 1979: CASR-4-80. (Unpublished study received Feb 20, 1980 under 1258-EX-12; submitted by Olin Corp., Stamford, Conn.; CDL:241820-A)

00028428 Olin Corporation (1972) Determination of Terraclor® and Terrazole® in Cotton Seed. Method CAM-11-72 dated Apr 4, 1972. (Unpublished study received Feb 20, 1980 under 1258-EX-12; CDL: 241820-B)

00064191 Kuchar, E.J. (1971) Residues of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole in Cotton Seed: CASR-3-71. (Unpublished study received Jul 22, 1971 under 0F0997; submitted by Olin Corp., Stamford, Conn.; CDL:111187-A)

00064194 Olin Corporation (1972) Residues of Terraclor-Super X in Cotton Seed--1971 Crop: CASR-7-72. (Unpublished study received Apr 19, 1972 under 0F0997; CDL:111184-A)

00093747 Kuchar, E.J.; Griffith, W.P.; Thomas, R.J. (1969) Analytical Investigations Concerned with Terraclor-Terrazole Cow Feeding Studies: CASR-4-69; 2483. Includes method CAM-1-69 dated Feb 1, 1969. (Unpublished study received Jan 20, 1982 under 1258-812; submitted by Olin Corp., Stamford, Conn.; CDL:070614-C)

00093748 Kuchar, E.J.; Griffith, W.P.; Thomas, R.J. (1971) Analytical Investigations Concerned with Terraclor-Terrazole Cow Feeding Studies: Residues of 3-Carboxy-5-ethoxy-1,2,4-thiadiazole: CASR-4-69, Supplement I; 2486. Includes method CAM-10-71 dated Jul 16, 1971. (Unpublished study received Jan 20, 1982 under 1258-812; submitted by Olin Corp., Stamford, Conn.; CDL:070614-D)

00093751 Thomas, R.J.; Dietrich, R.F.; Rittner, R.C. (1981) Metabolism of Terrazole®-14C in Corn Leaves: CASR-4-81; 3667. Includes method CAM-5-81 dated Feb 12, 1981. (Unpublished study received Jan 20, 1982 under 1258-812; submitted by Olin Corp., Stamford, Conn.; CDL:070614-G)

00093752 Olin Corporation (1981) (Residues of Terrazole® in Cow and Chicken Tissues, Eggs and Milk). Includes method CAM-47-81 dated Oct 16, 1981. (Compilation; unpublished study, including 3716 and 3725, received Jan 20, 1982 under 1258-812; CDL: 070614-H)

00093753 Wilkes, L.C.; Ward, G.M.; McConnell, A.B.; et al. (1981) Metabolism of Terrazole in Laying Hens: ADC Project No. 547; 3726. (Unpublished study, including published data, received Jan 20, 1982 under 1258-812; prepared by Analytical Development Corp., submitted by Olin Corp., Stamford, Conn.; CDL:070614-I)

00093754 Wilkes, L.C.; Ward, G.M.; McConnell, A.B.; et al. (1982) Metabolism of Terrazole in Lactating Goats: ADC Project No. 546; 3727. (Unpublished study, including published data, received Jan 20, 1982 under 1258-812; prepared by Analytical Development Corp., submitted by Olin Corp., Stamford, Conn.; CDL:070614-J)

00093755 Wilkes, L.C.; Ward, G.M.; Gustafson, D.E.; et al. (1982) Terrazole Poultry Feeding Study: ADC Project No. 648; 3728. (Unpublished study received Jan 20, 1982 under 1258-812; prepared by Analytical Development Corp., submitted by Olin Corp., Stamford, Conn.; CDL:070614-K)

00093756 Wilkes, L.C.; Ward, G.M.; Gustafson, D.E.; et al. (1982) Terrazole Poultry Feeding Study: ADC Project No. 648; 3729. (Unpublished study received Jan 20, 1982 under 1258-812; prepared by Analytical Development Corp., submitted by Olin Corp., Stamford, Conn.; CDL:070614-L)

43259601 Thiem, D. (1994) Multiresidue Study: Testing of Terrazole and Its Monoacid Metabolite Through FDA Multiresidue Protocols B, C, D, and E: Final Report: Lab Project Number: RP-94010: 1214. Unpublished study prepared by Colorado Analytical Research &

Development Corp. 412 p.

43305701 Blaszczyński, E.; Mertz, J. (1994) Terrazole: Response to EPA Data Call-In Requirement for Animal Storage Stability Data: Lab Project Number: 94100. Unpublished study prepared by Uniroyal Chemical Co., Inc. 18 p.

43940001 McManus, J. (1996) Metabolism of (carbon 14)-Etridiazole in Mature Cotton After Soil Treatment: Lab Project Number: 9394. Unpublished study prepared by Uniroyal Chemical Co. 106 p.

44054701 McManus, J. (1996) Metabolism of Etridiazole in Wheat Grown from Treated Seeds: Lab Project Number: 9359. Unpublished study prepared by Uniroyal Chemical Co., Inc. 111 p.

44285001 Gaydos, K. (1997) Freezer Storage Stability of Etridiazole and the 3-Carboxylic Acid of Etridiazole in Cotton: (Final Report): Lab Project Number: RP-95036: 004-47: CAL 004-47. Unpublished study prepared by Centre Analytical Labs. 233 p. {OPPTS 860.1380}

44285201 McManus, J.; Yacolucci, R.; Mertz, J. (1997) Metabolism of (carbon 14)-Etridiazole in Soybean as a Seed Treatment: (Final Report): Lab Project Number: 94101. Unpublished study prepared by Uniroyal Chemical Co. 166 p.

44285901 Maselli, C. (1997) Terraclor Super X on Raw and Processed Cotton: Processing Study: (Final Report): Lab Project Number: SL-95025: RP-95-025: RP-95025. Unpublished study prepared by S-L Agri-Development Co.; Coastal Ag Research; and Texas A&M University. 533 p.

44311401 Yu, W.; Nag, J.; Chan, J.; et al. (1997) Confined Accumulation Study on Rotational Crops with (carbon 14)-Etridiazole (Terrazole): (Final Report): Lab Project Number: 93182/9389:93276: 9389. Unpublished study prepared by ABC Labs California and Uniroyal Chemical Co., Inc. 540 p. {OPPTS 860.1850}

44453201 McManus, J. (1997) Metabolism of (carbon 14)-Etridiazole in Mature Cotton After Soil Treatment: (Final Report Amendment Number 1): Lab Project Number: 9394. Unpublished study prepared by Uniroyal Chemical Company, Inc. 5 p.